REMARKS / ARGUMENTS

Claims 1-7 are pending in the application. All pending claims stand rejected. In view of the following discussion, the applicants submit that all pending claims are in condition for allowance.

On page 2 the Examiner rejected claims 1-4 and 6 under 35 U.S.C. § 102(b) as being anticipated by Adjei et al., U.S. Pat. No. 6,261,539 ("the Adjei reference"). The applicants respectfully traverse the rejection. The Adjei reference does not disclose with sufficient specificity the range of water content of the claimed invention. Claim 1 recites a formulation comprising water in an amount of about 0.13 to about 0.18 percent (w/w) of the product formulation, at least one HFA as a propellant, one or more active ingredients, and one or more excipients. The Adjei reference teaches a formulation with a broad range of water content of 300 to 2000 ppm of the total aerosol formulation weight (equivalent to 0.03 to 0.2% w/w) and most preferred is from 500 to 700 ppm (equivalent to 0.05 to 0.07% w/w) but does not disclose any specific examples falling within the presently claimed range. Therefore, the narrower claimed water content range is not disclosed with sufficient specificity by the Adjei reference to constitute an anticipation of the claims. *See*, *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999 (Fed. Cir. 2006). Thus, claim 1 is not anticipated by the Adjei reference and is therefore allowable. Claims 2-4 and 6 which depend from claim 1 and recite further limitations are also not anticipated and are thus allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

On page 2 the Examiner maintained the rejection of claims 1-4 and 6 under 35 U.S.C. § 102(b) as being anticipated by Jager et al., WO 9413262 ("the Jager reference"). The applicants respectfully traverse the rejection. It appears the Examiner did not fully address the applicant's previous arguments in response to the remaining 35 U.S.C. § 102 rejections but rather applies the alleged lack of "unexpected results" to find anticipation (pages 8-9 of the Office Action). For the same reason as discussed in the previous Response filed on March 20, 2008, the Jager reference does not disclose with sufficient specificity the range of water content of the claimed invention. "If the claims are directed to a narrow range, and the reference teaches a broad range", as in the instant rejection, "it may be reasonable to conclude that the narrow range is not disclosed with 'sufficient specificity' to constitute an anticipation of the claims". MPEP § 2131.03. The Jager reference teaches an ipratropium MDI with a broad range of water content of

0 to 5% but does not disclose any specific examples falling within the presently claimed range. Therefore, the narrower claimed water content range is not disclosed with sufficient specificity by the Jager reference to constitute an anticipation of the claims. *See, id.* Thus, claim 1 is not anticipated by the Jager reference and is therefore allowable. Claims 2-4 and 6 which depend from claim 1 and recite further limitations are also not anticipated and are thus allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

On pages 3-4 the Examiner maintained the rejection of claims 1-4 and 6 under 35 U.S.C. § 102(b) as being anticipated by Lewis et al., EP 1219293 ("the Lewis reference") and under 35 U.S.C. § 102(e) as being anticipated by Ashurst et al., U.S. Pat. No. 6,511,652 ("the Ashurst reference"). The applicants respectfully traverse the rejections. Claim 1 is recited above. Neither of the cited references teach or suggest each and every element of the current invention. The Lewis reference discloses specific MDI formulations containing 0.1% of water. The Ashurst reference discloses an MDI with water content of 0.015 to 0.1% (although recited as 0.015 to 1% by the Examiner). The cited references disclose formulations with water content below the claimed range and therefore cannot anticipate claim 1. *Titanium Metals Corp. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985). Therefore, claims 1-4 and 6 are allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejections.

On page 5 the Examiner maintained the rejection of claims 1-2, 4 and 6 under 35 U.S.C. § 102(e) as being anticipated by Keller et al., U.S. Pat. No. 6,475,467 ("the Keller reference"). The applicants respectfully traverse the rejection. For the same reason stated above regarding the Jager reference, the Keller reference does not disclose with sufficient specificity the range of water content of the claimed invention. The Keller reference discloses only suspension formulations having water content of less than 1% but does not disclose any specific examples falling within the presently claimed range. Therefore, the narrower claimed water content range is not disclosed with sufficient specificity by the Keller reference to constitute an anticipation of the claims. Thus, claim 1 is not anticipated by the Keller reference and is therefore allowable. Claims 2, 4 and 6 which depend from claim 1 and recite further limitations are also not anticipated and are thus allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

On page 6 the Examiner maintained the rejection of claims 5 and 7 under 35 U.S.C. § 103(a) as being unpatentable over the Lewis reference in view of the Jager reference. The

applicants respectfully traverse the rejection. The criticality of the claimed range of about 0.13 to about 0.18% (w/w) renders claims 5 and 7 not obvious over the combination of the references. *In re Woodruff*, 919 F.2d 1575 (Fed. Cir. 1990). A combination of the references results in a range of water content from 0 to 5%. The applicants submit that the claimed range of water content from 0.13 to 0.18% is critical for achieving superior single actuation reproducibility of the suspension formulation over that of a broader range of water content. As water content falls below or above the claimed range, the reproducibility diminishes significantly.

The Examiner alleges the data submitted in the Declaration by George Destefano, filed on March 20, 2008, do not fully support the applicant's assertion of unexpected results. The Examiner specifically compared the amounts of albuterol sulfate (115.3, 118.31 and 119.26 μg) and ipratropium bromide (20.56, 20.22 and 21.31 μg) each obtained from a single actuation event from three different "cans" containing three different water contents 1500, 2500, and 3500 ppm, respectively, and concluded there was no significant difference. The applicants submit the unexpected result is not the difference in amounts of the active ingredients, released during one actuation event, between "cans" containing different water content. Rather, the unexpected result relates to reproducibility in a single "can" containing a specific water content to repeatedly provide the same amount of the active ingredients released from the same "can" over a series of single actuation events as a compared to a "can" containing a different water content. For the purpose of showing unexpected results, it is irrelevant whether "cans" containing different water contents release the same or different amounts of the active ingredients.

The applicants point to Figures 2 and 3 of Analytical Report AR-030012, submitted in the Declaration by George Destefano, which show the results of the reproducibility for "cans" containing various water contents to release the same amount of albuterol sulfate (i.e., % of theory) during a single actuation event. Cans containing 1500 to 2500 ppm water content (equivalent to 0.15 to 0.25% w/w) clearly show significantly better reproducibility than those cans containing 1200 ppm water content (equivalent to 0.12% w/w) or less. Thus, unexpected results are apparent for cans containing a formulation comprising water in an amount of about 0.13 to about 0.18 percent (w/w).

Therefore, in light of the above discussion, the claimed water content range is not obvious in light of the disclosure in the Lewis reference and the Jager reference. Thus, claims 5 and 7 which depend from claim 1 are not obvious over the Lewis reference in view of the Jager

reference and are therefore allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

On page 7 the Examiner maintained the rejection of claims 1-7 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Pat. No. 6,423,298 in view of the Lewis reference. The applicants respectfully traverse the rejection. For the same reason as stated above, the claimed invention is not obvious over the combination of the references. The '298 patent discloses a water content ranging from 0.0001 to 10%. The shortcomings of the Lewis reference are discussed above, i.e., a water content of 0.1%. The '298 patent does nothing to cure the deficiencies of the Lewis reference. A combination of the references could not teach a skilled artisan the criticality of the claimed water content since such combination results only in a range of water content from 0.0001 to 10%. Therefore, the narrower claimed water content range of claim 1 is not obvious in light of the disclosure in the '298 patent and the Lewis reference. Thus, claims 1-7 are not obvious over the '298 patent in view of the Lewis reference and are therefore allowable. Accordingly, the applicants respectfully request the Examiner to withdraw the rejection.

Applicants submit that all claims pending in the patent application are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fee for a RCE is included herewith. In the event there are any fees due and owing in connection with this matter, please charge same to our Deposit Account No. 11-0223.

Respectfully submitted,

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s/Timothy X. Gibson/
Timothy X. Gibson
Attorney for Applicant(s)
Reg. No. 40,618

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877
Tel.: (203) 798-4868